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SALIWANCHIK LLOYD & SALIWANCHIK

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT

PAPER NUMBER

1636

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 09/879,329             | SIGNER ET AL.       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Daniel M. Sullivan     | 1636                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 18-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8,9,19,20 is/are allowed.
- 6) ☒ Claim(s) 1-7,10-16,18 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/07</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This Office Action is a response to the Paper filed 27 November 2007 in response to the Non-Final Office Action mailed 1 August 2007. Claims 1-16 and 18-21 were considered in the 1 August Office Action. Claims 1, 4 and 21 were amended in the 27 November Paper. Claims 1-16 and 18-21 are pending and under consideration.

#### ***Response to Amendment and Arguments***

##### **Claim Rejections - 35 USC § 103**

Rejection of claims 1, 4, 6, 10, 12, 14, 15 and 18 under 35 U.S.C. 103(a) as being unpatentable over Bauer *et al.* and further in view of Ow, D. (WO 93/01283) for reasons of record and herein below in the response to Applicant arguments is **withdrawn** in view of the claim amendments.

Rejection of claims 2, 3, 5, 7, 11, 13, 16 and 21 under 35 U.S.C. 103(a) as being unpatentable over Bauer *et al.* (*supra*) and further in view of Ow (*supra*) as previously applied to claims 1, 4, 6, 10, 12 and 14, and further in view of Lassner et al. US Pub No. 2002/0035739 A1 is **withdrawn** in view of the claim amendments.

#### ***New Grounds Necessitated by Amendment***

##### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1636

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 10-16, 18 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson et al. US Patent No. 6,984,774 B1 in view of Bauer *et al.* US Patent No. 6,984,774 B1 (previously made of record) and further in view of Lassner et al. US Pub No. 2002/0035739 A1 (previously made of record).

Independent claim 1 is directed to a genetic construct for use in transforming host plant cells, comprising: a. a positive selectable marker gene that when transformed into the host plant cells facilitates growth on a positive selective medium that is complementary to the positive selective marker gene, b. a negative selectable marker gene that when rendered operable in the host plant cells hinders growth on a negative selective medium that is complementary to the negative selectable marker, the negative selectable marker being different in kind from the positive selectable marker, and c. two direct repeats of a gene of interest, each direct repeat comprising a nucleic acid sequence encoding a peptide, wherein the peptide is capable of being expressed in said plant cells, with the direct repeats immediately flanking the positive and

Art Unit: 1636

negative selectable marker genes of (a) and (b). Independent claim 21 is directed to a genetic construct having the limitations of claim 1 and further recites that the negative selectable marker gene is CodA.

In Figure 1, Peterson et al. teaches a genetic construct for transforming host plant cells comprising a positive selectable marker gene that when transformed into host plant cells facilitates growth on a positive selective medium that is complementary to the positive selective marker gene (i.e., NPT II) and two direct repeats of a gene of interest, each direct repeat comprising a nucleic acid sequence encoding a peptide (i.e., GUS), wherein the peptide is capable of being expressed in said plant cells, with the direct repeats immediately flanking the selectable marker gene. (See also column 3, examples B., C. and D. and paragraphs 4-5 in column 4.) In the construct illustrated in Figure 1, recombination is detected by reconstitution of the GUS gene, which provides for marker rescue of cells in which recombination has occurred. However, Peterson et al. teaches that genes other than marker genes can be used as the gene of interest (see, e.g., the fourth full paragraph in column 5) and teaches detection of marker deletion as an alternative to marker rescue as a means to identify recombination events (see especially column 5, lines 63-67).

Thus, Peterson et al. teaches a genetic construct comprising all of the elements of the instant independent claims except for an explicit teaching of including a negative selectable marker gene in the region flanked by the direct repeats (claim 1), wherein the negative selectable marker gene is CodA (claim 21), and further suggests marker deletion as a means to detect recombination.

Bauer *et al.* teaches a genetic construct comprising a positive selectable marker gene and a negative selectable marker gene, different in kind from the positive selectable marker, and direct repeats of a gene of interest that flank the positive and negative selectable marker genes (see especially the paragraph beginning at line 34 in column 3 and the paragraph bridging columns 3-4). Furthermore, in the paragraph bridging columns 10-11, Bauer *et al.* teaches a method of removing a selectable marker comprising transforming cells with the genetic construct disclosed therein, identifying transformants using the integration marker (*i.e.*, positive selection marker) and then selecting cells that have lost the negative selection marker by culturing in negative selection medium. (*I.e.*, selection by marker deletion.) Thus, Bauer *et al.* teaches that when recombination events are selected by marker deletion, a negative selectable marker gene is positioned between the direct repeats so that the negative selectable marker gene is deleted by the recombination event.

Lassner *et al.* teaches, “Examples of negatively selectable markers useful in the context of plant genetic engineering include a number of genes involved in herbicide metabolism, including...codA...” (Paragraph 0033.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the genetic construct of Peterson *et al.* by the insertion of a negative selectable marker gene between the direct repeats of a gene of interest comprised by the construct as described in the teachings of Bauer *et al.* One would have been motivated to combine the elements of the prior art because Peterson *et al.* teaches marker deletion through recombination as an alternative means of identifying cells in which recombination events have occurred and Bauer *et al.* teaches that detection by marker deletion involves the insertion of a

Art Unit: 1636

negative selectable marker gene between the direct repeat sequences. One would have been motivated to use marker deletion strategy described by Bauer et al. to carry out marker deletion type detection of recombination events as suggested by Peterson et al. because the process of Bauer et al. was known in the art at the time of invention as an effective means to identify cells comprising recombined constructs.

In view of the foregoing, a genetic construct having all of the limitations of the genetic construct of the instant claim 1 would have been obvious to one of ordinary skill in the art at the time the invention was made. Furthermore, as the method of detecting recombination events described in the paragraph bridging columns 10-11 of Bauer et al. comprises all of the elements of the process recited in independent claim 4, the process of claim 4 would also have been obvious to one of ordinary skill in the art at the time of invention.

Still further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Peterson et al. in view of Bauer et al. to use *codA* as the negative selectable marker gene because Lassner et al. teaches that *codA* is a negatively selectable marker gene that was known in the art to be useful for plant genetic engineering. One would have been motivated to use the *codA* marker gene and one would have had a reasonable expectation of success in using the *codA* marker gene in view of the teaching of Lassner et al. that the *codA* gene was established as an effective negative selectable marker useful in plant genetic engineering.

Absent evidence to the contrary, one would have a reasonable expectation of success in combining the prior art elements because each of the elements were known to be operative

Art Unit: 1636

independently and all that is required is that the elements in combination retain their known prior art functions.

Thus, the products and processes of independent claims 1, 4 and 21 would have been obvious to one of ordinary skill in the art at the time the invention was made. Furthermore, the limitations of the dependent claims are also found in the cited teachings or would be obvious over the teachings found therein. As described above, Lassner et al. teaches the use of a CodA negative selectable marker according to dependent claims 2, 5, 7, 11 and 16 and Peterson et al. teaches a positive selectable marker that is NPTII according to claim 3. Furthermore, Peterson et al. teaches that the products and processes described therein can be used in many of the species set forth in claim 18. (See especially column 5, lines 30-42.)

Claims 6, 10, 12 and 14 are directed to the genetic construct of claim 1, wherein the positive and negative selectable markers are limited to specific arrangement within the construct with respect to one another (*e.g.*, GI-PS-NS-GI *versus* GI-NS-PS-GI). Claims 14-16 are further limited to comprising additional genes of interest flanking the gene of interest present as a direct repeat. Although Bauer *et al.* does not explicitly teach any particular configuration of the positive and negative selectable markers, other than that they should be flanked by the direct repeat, the skilled artisan would not expect that the arrangement of the selectable markers within the boundaries of the direct repeat would affect the function of the construct in any way.

A *prima facie* case of obviousness may be made when chemical compounds have very close structural similarities and similar utilities because one skilled in the art would be motivated by the expectation that compounds of similar structure will have similar function (see *e.g.*, MPEP 2144.09). Thus, it would be *prima facie* obvious to the skilled artisan to use either of the



Art Unit: 1636

configurations of positive and negative selectable markers set forth in the claims. With regard to additional genes of interest, Peterson et al. teaches that the recombination constructs might further comprise, at least, a gene encoding a transposase (see especially column 4, lines 59-61). Thus, claims 6, 10, 12 and 14-16 would also have been obvious over the cited art.

In view of the foregoing, the invention of claims 1-7, 10-16, 18 and 21, as a whole, would also have been obvious to one of ordinary skill in the art at the time the invention was made. Therefore, the claims are properly rejected under 35 USC § 103(a).

#### *Allowable Subject Matter*

Claims 8, 9 and 19-20 are allowed.

#### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 1636

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M. Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D. can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) (<http://pair-direct.uspto.gov>) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Daniel M. Sullivan/  
Primary Examiner  
Art Unit 1636